

General Remarks to Accompany the Report of Subcommittee 3
Genetic Information Identified in Research
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For this subcommittee several questions seemed most pertinent. First, to what extent was genetic information (however defined, but generally perceived to be DNA sequence information and inferences obtainable by family history) a protected category that could not be used to determine if insurance could be denied to an individual? Second, did the source of the information matter in this regard (whether derived from specific clinical testing or from research studies)? Third, if protection was concluded to be in force, what remedies are available to the individual if this information was used in an improper fashion?

The following is a brief summary of the provisions of Washington State Law that appear to cover genetic information and its use and consequences of improper use.

In April 2002, the the Governor signed Senate Bill 5207 which adds the phrase “including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs” to the definition of Health Care Information so that the definition now reads:
“(6) "Health care information" means any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care, **including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs**. The term includes any record of disclosures of health care information.

Health care providers or facilities shall chart all disclosures, except to third-party payors, of health care information, such chartings to become part of the health care information.” (RCW 70.02.010)

The use of genetic information in the issuance of **health insurance** is limited in the following manner.
WAC 284-43-720

..... health carriers may not reject health plan applicants and may not limit or exclude plan coverage for any reason associated with health risk or perceived health risk except for the imposition of a preexisting condition exclusion as permitted in this chapter.

(3) Genetic information shall not be treated as a health condition in the absence of a diagnosis of the condition related to such information. (Emphasis added)

The disclosure of “health care information” is limited in the following manner:

RCW 70.02.020

Disclosure by health care provider.

Except as authorized in RCW 70.02.050, a health care provider, an individual who assists a health care provider in the delivery of health care, or an agent and employee of a health care provider may not disclose health care information about a patient to any other person **without**

the patient's written authorization. A disclosure made under a patient's written authorization must conform to the authorization.

RCW 70.02.045

Third-party payor release of information.

Third-party payors shall not release health care information disclosed under this chapter, except to the extent that health care providers are authorized to do so under RCW 70.02.050.

Some materials can be used for research under the following conditions:

RCW 70.02.050

Disclosure without patient's authorization.

(g) For use in a research project that an institutional review board has determined:

(i) Is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure;

(ii) Is impracticable without the use or disclosure of the health care information in individually identifiable form;

(iii) Contains reasonable safeguards to protect the information from redisclosure;

(iv) Contains reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research project; and

(v) Contains procedures to remove or destroy at the earliest opportunity, consistent with the purposes of the project, information that would enable the patient to be identified, unless an institutional review board authorizes retention of identifying information for purposes of another research project;

The remedies available to a person whose health care information has been disseminated without permission are defined in the bill:

RCW 70.02.170

Civil remedies.

(1) A person who has complied with this chapter may maintain an action for the relief provided in this section against a health care provider or facility who has not complied with this chapter.

(2) The court may order the health care provider or other person to comply with this chapter. Such relief may include actual damages, but shall not include consequential or incidental damages. The court shall award reasonable attorneys' fees and all other expenses reasonably incurred to the prevailing party.

(3) Any action under this chapter is barred unless the action is commenced within two years after the cause of action is discovered.

(4) A violation of this chapter shall not be deemed a violation of the consumer protection act, chapter 19.86 RCW.

It is not clear that there is any reason to consider “genetic information” contained through participation in research different from that obtained through clinical testing or taking of a family history. For federally funded research 45CFR46 characterizes how and what information is to be kept confidential. If this is assumed to have the character of “medical information” as discussed above, then all the provisions of Washington law and administrative code apply. One aspect of testing that may apply in this regard is the relatively new insistence that if genetic information obtained in the course of research is to be reported to the subject, testing must be performed in a CLIA certified or otherwise approved laboratory. This, on the surface, would appear to place such information in a “patient” context and as “medical information”. Less clear would the situation if the genetic information derived in the course of research studies was released inadvertently, or deliberately, or deduced to apply to an individual on the basis of data provided in a publication. If this is considered in the same light as “medical information” then all aspects of the discussion above apply. If not, then the coverage is not immediately clear. In Washington, the prohibited use of “genetic information” to exclude medical insurance coverage does not specify the source of the information and thus coverage should be available.

The remedies available to the individual would all seem to derive from state law at present as there is currently no general federal provision, other than the Executive Order which applies to the Federal Government, that provides remedies for the improper use of genetic information, and save the ADA statute in which the application to “genetic information” in the absence of physically diagnostic findings would have to be covered under the “perception of disability” provision of the law, which has not been tested in this venue.

All these considerations depend on the idea that “genetic discrimination” is sufficiently widespread to warrant legislative intervention to “prevent” the activity and “punish” the wrongdoer while providing remediation. We had no evidence presented to the committee as a whole that any discrimination on the basis of genetic information derived from research (or other source) had occurred in the State of Washington. It has been pointed out to us that the absence of evidence of this occurrence does not mean that it does not and has not occurred and there has been the underlying assumption, backed by assertions of many instances in other venues, that of course it is occurring. In the absence of a careful and considered analysis of this information, it is extremely difficult to characterize these events and thus to determine the nature, if any, of untoward events and whether current law provides sufficient remediation if damaging actions have occurred. The assertion that such actions do not occur is equally opaque to analysis.

One of the abiding concerns is that the use of “genetic information” could prevent access to insurance of various kinds. Of these, health insurance is probably most pressing and most likely to be seen as a necessity rather than a luxury. Other forms of insurance, such as automobile insurance, are necessities in this age. Yet others, like life insurance, have functional

equivalents (savings plans) that can provide partial or entire coverage at the same level and for the same costs. “Discrimination” on the basis of genetic information describes instances in which a “scarce” resource is allocated in a manner that is determined, at least in part, by that information. One alternative to creating new legislation that may impose unforeseen burdens is to modify the resource so that it is no longer scarce. In this case, a form of universal health insurance would eliminate the health benefits limitation. The issues about invasion of privacy are not met, but might be dealt with in another fashion.

THESE VIEWS MAY NOT REPRESENT THOSE OF ALL MEMBERS OF THE
SUBCOMMITTEE; INDEED, THEY PROBABLY DO NOT.

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July 31, 2002
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